

FAP 2236

ENVIRONMENTAL ASSESSMENT

1. August 16, 1996
2. Betty Pendleton
3. 15505 Country Ridge Drive
Chesterfield, MO 63017
4. To amend 21 CFR 573.280 for the addition of sodium stearate.

This environmental assessment was prepared in accordance with 21 CFR 25.31a(a) as modified by 21 CFR 25.31a(b)(5) for naturally occurring substances.

21 CFR 573.280 presently allows the use of calcium stearate as an anti-caking agent in animal feeds.

Feed-grade calcium stearate is the calcium salt of a fatty acid mixture that is predominately stearic acid. Sodium stearate is the sodium salt of a fatty acid mixture that is predominately stearic acid.

Sodium Stearate will be purchased from Barlocher, Munich, Germany, where the product is produced. The product will be sold to and used by manufacturers of animal feeds. Feed mills are generally located in agricultural areas.

Sodium stearate will be used as a substitute for calcium stearate.

The production of sodium stearate is in conformance with local and federal regulations and requirements of Munich, Germany.

The use of sodium stearate is not expected to alter significantly the concentration and distribution of the product, its metabolites, degradation products, or its constituent parts in the environment. The amount of sodium stearate used in animal feeds will not increase its constituent parts into the environment because the use of sodium stearate will be replacing calcium stearate, therefore an increase in the use of stearic acid is not expected to occur. It is not expected that the concentration of product being used will change the environment because the calcium salt is already approved and being used.

An analysis of the environmental properties of stearic acid demonstrates that these salts relatively innocuous, naturally-occurring compounds which are commonly present throughout the environment.

Neither the production process nor the production volume will change as a result of the approval of this Food Additive Petition.

I certify that the information presented is true, accurate, and complete to the best of my knowledge.

